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10/083,476	02/27/2002	Roger N. Piasio	ISA-102.01	4777

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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08/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/083,476

Applicant(s)

PIASIO ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22 is/~~are~~ pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 is/~~are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 03/05/07.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendments

- 1) Acknowledgment is made of Applicants' amendments filed 03/05/07, 05/17/07 and 06/26/07 in response to the non-final Office Action mailed 12/05/06. With this, Applicants have amended the specification and the claims.

Status of Claims

- 2) Claim 22 has been amended via the amendment filed 06/26/07.
Claim 22 is pending.

Information Disclosure Statement

- 3) Acknowledgment is made of Applicants' information disclosure statement filed 03/05/07. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 6) The objection to the specification made in paragraph 9(a) of the Office Action mailed 12/29/05 and paragraph 7 of the Office Action mailed 12/05/06 is withdrawn in light of Applicants' amendment to the specification.
- 7) The objection to the specification made in paragraph 9(b) of the Office Action mailed 12/29/05 and paragraph 8 of the Office Action mailed 12/05/06 is withdrawn in light of Applicants' amendment to the specification.

Objection(s) Maintained

- 8) The objection to the specification made in paragraph 3 of the Office Action mailed 7/27/04 and

maintained in paragraph 8 of the Office Action mailed 12/29/05 and paragraph 6 of the Office Action mailed 12/05/06 is maintained for reasons set forth therein.

Rejection(s) Withdrawn

9) The rejection of claim 22 made in paragraph 13 of the Office Action mailed 12/05/06 under 35 U.S.C § 112, first paragraph, as containing new matter, is withdrawn. A new/modified rejection is set forth below to address the claim as amended.

10) The rejection of claim 22 made in paragraph 14(a) of the Office Action mailed 12/05/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 22 made in paragraph 14(b) of the Office Action mailed 12/05/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claim 22 made in paragraph 14(c) of the Office Action mailed 12/05/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claim 22 made in paragraph 14(d) of the Office Action mailed 12/05/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claim 22 made in paragraph 14(e) of the Office Action mailed 12/05/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, withdrawn in light of Applicants' amendment to the claim.

15) The rejection of claim 22 made in paragraphs 14(f) and 14(h) of the Office Action mailed 12/05/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

16) The rejection of claim 22 made in paragraph 14(g) of the Office Action mailed 12/05/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herein below.

Applicants state that 'non-bound complexes' refer to any complexes not bound to the at least one scrub zone. However, the instant specification as filed does not contain such a limiting definition for the term. The limitation is still indefinite and confusing. Note that the earlier recited mixture includes 'the complexes' as opposed to 'any non-bound complexes'. How 'non-bound complexes' recited in line 16 of the claim differs in scope with the 'non-bound complexes' recited in line 19 of the claim is not clear.

New Rejection(s) Necessitated by Applicants' Amendment

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

17) Claim 22 is rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 22, as amended, is drawn to a method for detecting a symptomatic *Streptococcus pneumoniae* infection in a subject. The amended claim includes the limitations: 'flowing the urine sample along the bibulous strip'; 'mobilizing a tagged antibody capable of binding the C-polysaccharide antigen of *Streptococcus pneumoniae*'; the tagged antibody having been present in 'a dried state on the bibulous strip to form a mixture comprising the urine sample and the mobilized tagged antibody'; 'binding the tagged antibody and the antigen ... to form complexes' in the mixture; 'flowing the mixture, including the complexes if formed, further along the bibulous test strip'; 'binding at least one of the complexes, if present, to antibodies specific for the complexes immobilized in at least one zone along the bibulous test strip'; 'flowing the mixture comprising any non-bound complexes, if present, downstream of the at least one scrub zone'; and 'binding, to antibodies specific for the complexes immobilized in a capture zone downstream of the at least one scrub zone, any non-bound complexes if present, wherein color formation in the downstream capture zone resulting from the binding is indicative of a symptomatic *Streptococcus pneumoniae* infection in the subject'.

Applicants submit that pages 8 and 9 as well as the Examples of the specification provide support for the limitations of claim 22. However, there is not adequate descriptive support in the instant specification as filed for the now claimed method. Applicants state that the claim is 'mechanical in nature, and thus has a lower written description threshold that does not require *ipsis verbis* support for

the limitations'. Claim 22 is not drawn to a mechanical device, but to a method. Applicants have not provided the legal basis for their statement that a claim that is mechanical in nature has a lower written description threshold. The same standard is applicable to every claim under 35 U.S.C. § 112, first paragraph. The limitations 'tagged antibody having been present in a dried state on the bibulous strip', 'complexes in the mixture', 'including the complexes if formed', 'at least one of the complexes, if present', 'at least one scrub zone', 'non-bound complexes', 'the mixture comprising non-bound complexes, if present', 'any non-bound complexes if present' and 'antibodies specific for the complexes' are not supported in the specification, as originally filed. The above-identified limitations in the claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

18) Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 22, as amended, is vague, indefinite, and inconsistent in the limitations: 'a subject' (see line 2) and 'a human subject of age 12 years or less' (see lines 3 and 4). The two limitations are not of same scope, because the former includes a non-human subject of any age.

(b) Claim 22 is indefinite in the limitation 'the complexes' (see line 18) because it is unclear where does this limitation derive antecedence from. Are these earlier recited 'complexes' or 'non-bound complexes'?

(d) Claim 22 is indefinite in the limitation: 'wherein color formation in the downstream capture zone resulting from the binding is indicative'. Binding of what element to what other element results in color formation in the downstream capture zone is not clear.

Remarks

19) Claim 22 stands rejected.

21) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

23) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

24) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

August, 2007


S. DEVI, PH.D.
PRIMARY EXAMINER